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Reflections on the National Patient Safety Agency's database of medical errors

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It was a decade ago that we, writing in this Journal, made the call for the urgent development of a national database of medical error; the vision was that this would help the medical fraternity better understand the epidemiology of iatrogenic harm, define research priorities in this area and develop error reduction strategies.¹ This call arose out of the recommendations of two key reports from the United States and Australia, which highlighted the need for patient safety to be an integral part of health policy considerations.^{2,3} In this article, we reflect critically on the progress that has been achieved with respect to the creation of the National Patient Safety Agency's (NPSA) Reporting and Learning System (RLS).

Domestic and international health policy have prioritized the importance of reducing the burden of iatrogenic harm, the latter mandate coming through the World Health Organization's (WHO) World Alliance for Patient Safety.⁴ One of the initiatives consistently identified as of highest priority in such deliberations has been the need for the creation of patient safety reporting systems (PSRS) – this favourable policy climate has enabled several such systems to have been created in countries such as Australia, Germany, some states in the USA and the UK (England and Wales).⁵

The Department of Health has been spearheading the patient safety agenda through the creation of the NPSA as a special designated strategic health authority; the NPSA has been charged with the creation of the development of the RLS database of patient safety incidents.⁶ Running since 2003, this database is now the largest of its kind in the world, already having received over three million reports of episodes of care that could or did result in iatrogenic harm.⁷ Reports continue to

accrue at an accelerating report, with the database currently receiving approximately 250,000 cases per quarter.

The largest proportions of these case reports originate from medical specialties (34%), surgical specialties (16%), mental health (13%), and obstetrics and gynaecology (10%). Of note is that the proportion of reports arising from primary care has been particularly low (5%), for reasons that as yet remain poorly understood. Data from the RLS are published in a number of formats including summative quarterly reports for England and Wales and, more recently, individual organizational reports showing reporting rates benchmarked against other similar organizations.⁸

When first envisioned the underlying model was simple: it would be a fully mandatory reporting scheme for medical errors.⁹ The main arguments for mandatory systems is that these allow a truly comprehensive picture of the patient safety landscape to emerge and furthermore that these improve healthcare professionals sense of accountability. It has however subsequently been noted that mandatory systems deter practitioners and hospitals from reporting incidents as they fear public disclosure will lead to possible comeback for the reporting physician or trust.¹⁰

The NPSA did consider a mandatory reporting model, but in the end opted for a voluntary anonymized reporting structure in the hope of enabling fuller disclosure of incidents without fear of reprisal on the part of the individual making the report.⁹ The approach being used allows patient safety incidents to be reported via a web-based open access system¹¹ or the more popular system whereby reports are submitted in an anonymized fashion from the individual organization's local risk management system.

Table 1
Rapid Response reports to date¹⁵

| <i>Date</i> | <i>Topic</i> | <i>Title</i> |
|---------------|---|--|
| 11 Mar 2009 | Hip cement | Mitigating surgical risk in patients undergoing hip arthroplasty for fractures of the proximal femur |
| 19 Feb 2009 | Bowel cleansing solutions | Reducing risk of harm from oral bowel cleansing solutions |
| 09 Dec 2008 | Midazolam | Reducing risk of overdose with midazolam injection in adults |
| 26 Nov 2008 | Resuscitation, mental health, learning disability | Resuscitation in mental health and learning disability settings |
| 12 Nov 2008 | Craniotomy, burr holes, neurosurgery | Avoiding wrong-side burr holes/craniotomy |
| 21 Oct 2008 | Hib vaccine, Infanrix, immunization | Risks of omitting Hib when administering Infanrix-IPV+Hib |
| 30 Sep 2008 | Haemodialysis, water supply | Risks to haemodialysis patients from water supply (hydrogen peroxide) |
| 11 Aug 2008 | Vinca Alkaloid, minibag | Using Vinca Alkaloid Minibags (adult/adolescent units) |
| 28 July 2008 | Infusions, arterial lines | Problems with infusions and sampling from arterial lines |
| 19 May 2008 | Chest drain, chest tube | Risks of chest drain insertion |
| 24 April 2008 | Intravenous, IV, Heparin flush | Risks with intravenous heparin flush solutions |
| 22 Jan 2008 | Oral anti-cancer medicines | Risks of incorrect dosing of oral anti-cancer medicines |
| 26 Nov 2007 | Paraffin skin products | Fire hazard with paraffin-based skin products on dressings and clothing |
| 10 Sep 2007 | Haemorrhage | Emergency support in surgical units: dealing with haemorrhage |
| 03 Sep 2007 | Injectable amphotericin | Rapid Response Report 2: Risk of confusion between non-lipid and lipid formulations of injectable amphotericin |
| 18 June 2007 | Cytarabine | Rapid Response Report: Risk of confusion between cytarabine and liposomal cytarabine (Depocyte [®]) |

Analysis of these incidents by the NPSA has helped lead to the identification of possible solutions to these problems (Table 1). While these have proved useful, there remain several challenges associated with analysis and interpreting of data, these largely reflecting issues with the architecture of the RLS. The approaches used for analyses include stratified sampling of frequently occurring incident type and free text data mining of specific topics. The very large number of case reports being received renders it difficult to undertake detailed analysis of all incidents.¹² Such analysis is also compromised by the lack of detail in many of the reports received and, because reports are anonymized, the lack of opportunity to easily go back to those making the reports or to case-notes to identify further information.

The gross under-reporting to the database has been cited as its Achilles heel and as such its use is often limited to warning, communication and detection of rare patient safety incidents.¹³ While this may be a valid criticism, it is clear that reporting is increasing as clinicians become more aware

of its presence and furthermore develop confidence that there will not be any personal repercussions to making reports. Convincing clinicians of the usefulness of the data they contribute should in due course further increase the frequency and quality of reporting.

The problem of under-reporting in primary care has already been noted and needs to be addressed. Also of relevance in this context is the varying degree of engagement by different professional groups. In particular, nurses are good reporters; in contrast, consultants are very poor reporters. Consequently, clinical problems tend to be under-reported, while other potentially less serious non-clinical problems are perhaps over-represented. It is still proving difficult to engage senior clinicians in a generic reporting system. In order to try and overcome these problems, the RLS has been engaging frontline and senior clinicians and undertaking two pilot projects aimed at improving reporting from general practice and anaesthesia. Working with the Royal College of Anaesthetists and the Royal College of General Practitioners, two

bespoke reporting systems have been developed. Encouragingly, the former has been a success and there has been a significant improvement in the level of reporting from consultants.¹⁴ The impact of the latter work with the Royal College of General Practitioners is currently being assessed.

Initially the NPSA produced detailed patient safety solutions that, when evaluated, proved difficult for organizations to implement. Over the past 18 months, simpler solutions have been developed using a one-page format which outlines the problems and describes actions that can be taken to help prevent other patients being similarly harmed. NHS organizations are now also provided with supporting information that describes in considerable detail the relevant contextual data from the reporting system together with advice on implementation considerations. These 'Rapid Response' reports cover a wide range of issues from resuscitation in mental health to the risks of amphotericin toxicity to the latest guidance on the risk of bone cement implantation syndrome in hip fracture surgery (Table 1). There is thus good breadth and depth in the coverage of topics. Clear guidance has also been offered on how to prevent patient safety incidents that could arise from frequently performed procedures such as the insertion of chest drains.

The challenges to improving patient safety in healthcare remain significant. Our national database represents an important step and resource in ensuring that information about adverse events are both learned from and shared throughout the NHS. All clinicians, regardless of specialty, can contribute to these efforts by reporting patient safety incidents to the RLS. While important challenges remain in relation to encouraging fuller, franker and more comprehensive reporting, and then meaningfully analysing these data, it is we believe fair to conclude that very substantial progress has been made. As a clear leader in reporting systems, the successes and failures of the RLS are likely to have major implications on reporting systems in other parts of the UK and internationally, and so it is we suggest very much in the collective interests of patients nationally and internationally that we, irrespective as a profession

engage with, report to and make use of this resource to the best of our ability.

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